Date of Approval:July 29, 2012

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-482

AMPROMED for Calves
(amprolium)

9.6% Oral Solution

Cattle/Calves

As an aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in calves.

Sponsored by:

Cross Vetpharm Group Ltd.

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I. GENERAL INFORMATION:

A. File Number:	ANADA 200-482
B. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Rd., Tallaght, Dublin 24, Ireland Drug Labeler Code: 061623 U.S. Agent: Linda Duple Bimeda, Inc. 2836 Dolliver Park Avenue Lehigh, IA 50557
C. Proprietary Name:	AMPROMED for Calves
D. Established Name:	Amprolium
E. Pharmacological Category:	Anticoccidial
F. Dosage Form:	Oral solution
G. Amount of Active Ingredient:	96 mg/mL (9.6%)
H. How Supplied:	128 oz (1 gal) bottle
I. How Dispensed:	OTC
J. Dosages:	Prevention: 5 mg/kg per day for 21 days in drinking water or as a drench Treatment: 10 mg/kg per day for 5 days in drinking water or as a drench
K. Route of Administration:	Oral
L. Species/Class:	Cattle/Calves
M. Indications:	As an aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in calves.
N. Reference listed new animal drug:	CORID; amprolium; NADA 013-149; Huvepharma AD

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product AMPROMED (amprolium) for Calves 9.6% Oral Solution. The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The RLNAD was approved for use in chickens, turkeys, and calves on June 20, 1962.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

The following are assigned to this product for calves:

- Tolerances for Residues:
  The tolerances established for the pioneer product apply to the generic product. Tolerances are established under 21 CFR 556.50 as follows for residues of amprolium in calves (edible tissues): 2.0 parts per million in uncooked fat, 0.5 part per million in uncooked muscle tissue, liver, and kidney.

- Withdrawal Times:
  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the RLNAD product.

  A withdrawal period of 24 hours has been established for amprolium in calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

- Regulatory Method for Residues:
  The validated regulatory analytical method for detection of residues of amprolium is a fluorimetric test. A description of the regulatory method is filed in the Food Additives Analytical Manual that is on file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to AMPROMED:

- WARNING: Not for human use. Keep this and all drugs out of reach of children.
- PRECAUTIONS: May cause eye irritation. For irritation, flush with plenty of water; get medical attention.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that AMPROMED, when used according to the label, is safe and effective.